REMARKS

Claims 53, 56-62 and 87-99 were pending in the subject application. Applicants have, hereinabove, amended claims 53, 87 and 97. The amendments to the claims present no new matter and are supported by the specification and the originally filed claims. Accordingly, claims 53, 56-62 and 87-99 are now being examined.

Support for amended claims 53, 87 and 97 can be found in the specification as follows:

Support for amended claim 53 can be found in the originally filed specification, for example, at page 27, lines 29-31; page 28, lines 1-3; page 33, lines 8-13; and original claims 12 and 13.

Support for amended claim 87 can be found in the originally filed specification, for example, at page 58, lines 20-27; page 79, lines 1-21; and original claims 25 and 26.

Support for amended claim 97 can be found in the originally filed specification, for example, at page 27, lines 29-31; page 28, lines 1-3; page 33, lines 8-13; and original claims 12 and 13.

SPECIFICATION

In paragraphs 5 and 6, the Patent Office requested amendment of the specification to: a) add the SEQ ID numbers and b) update the first line of specification to reflect the current status of two of the referenced applications. In response, Applicants have amended the specification hereinabove.

REJECTIONS WITHDRAWN

In paragraphs 7-16, the Patent Office noted rejections previously made that have now been withdrawn. Applicants acknowledge and thank the Examiner for consideration of their arguments and withdrawal of the following rejections:

- Claims 53-63 and 87-88 under 35 U.S.C. §112, second paragraph;
- Claim 87 under 35 U.S.C. §112, first paragraph;
- Claims 53, 56-62 and 87-88 under 35 U.S.C. § 112, first paragraph;
- Claims 53, 56-62 and 88 under 35 U.S.C. §112, first paragraph;
- Claims 1, 53-60, 87 under 35 U.S.C. §102(e) as being anticipated by Au-Young;
- Claims 53 and 87 under 35 U.S.C. §102(a) as being anticipated by Reiter et al.;
- Claims 53, 56-62 and 87 under 35 U.S.C. 102(a) as being anticipated by Reiter (WO98/40403);
- Claims 1, 53-63, 87-88 under 35 U.S.C. § 103(a) as being unpatentable over Au-Young in view of Vitetta et al.;
- Claims 1, 53, 55, 60, 61, 63, 87-88 under 35 U.S.C. §103(a) as being unpatentable over Reiter et al. in view of Vitettta et al. and Thomas et al.;
- Claims 1, 53-63, 87-88 under 35 U.S.C. § 103(a) as being unpatentable over Reiter et al.

PRIORITY

Applicants acknowledge the priority given the claims by the Examiner (see paragraph 17); namely, December 1998 for claims 53, 56-62 and 87-88 and March 1998, for claims 90, 92, 93, 94, 96 and 97.

DOUBLE-PATENTING

In paragraph 18, the Patent Office provisionally rejected claims 53, 56-62, 87-88 and 89-99 under the judicially created doctrine of obviousness-type double patenting in view of

claims 1-3, 69-86 of copending application number 09/359,326, and also in view of claims 1-3 of U.S. Patent No. 6,258,939 in further view of Vitetta et al. and Queen et al.

Should the pending claims be found patentable, Applicants will submit a terminal disclaimer as appropriate.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

In paragraph 20a, the Patent Office rejects claims 53, 56-62, 87-99, under 35 U.S.C. § 112, second paragraph. The Examiner alleged that these claims are indefinite for reciting "monoclonal antibody designated . . .produced by the hybridoma designated" and asked "Does the claim mean that the antibody that binds to the epitope is produced by the hybridoma designated in the claim or are antibodies 1G8 etc produced by the hybridomas recited in the claims?".

Applicants have amended claims 53 and 97, from which the other claims depend, to identify which set of antibodies are produced by the designated hybridomas. Applicants believe that the claim, as herein amended, clearly states that antibodies 1G8, 2A2, 2H9, 3C5, 3E6, 3G3 or 4A10, are the antibodies produced by the designated hybridomas. In view of the amendment, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph.

In paragraph 20b, the Patent Office reject claim 87 under 35 U.S.C. §112, second paragraph, because of the recitation of "effective amount," without a stated function to be achieved.

Applicants have amended claim 87 to eliminate the use of "an effective amount" from the claim. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claim 87 under 35 U.S.C. §112, second paragraph.

In paragraph 20c, the Patent Office rejects claim 87 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for reciting 'binds to the extracellular domain of SEQ ID NO:2' because the exact meaning of the phrase is not clear.

Applicants respectfully disagree with this rejection. Contrary to the Examiner's assertion, the specification, indeed, provides sufficient guidance to one of skill in the art to determine the extracellular domain of SEQ ID NO:2. Given the entire sequence, as well as hydrophobicity plots and other information regarding the protein, one of skill in the art would readily determine those regions to which claim 87 refers. However, in order to further the prosecution of the subject application, Applicants herein amend claim 87 to remove reference to extracellular domain. Thus, the rejection is moot and Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

REJECTIONS UNDER 35 U.S.C. §102

In paragraph 21, the Patent Office rejects claims 53, 56-62, 87, 89, 91, 95, 98 under 35 U.S.C. §102(a) as being anticipated by Reiter et al. (WO 98/40403). According to the Examiner, "Reiter et al. teach the antibodies bind to distinct epitopes and epitope mapping for antibodies recited in claim 53 and compositions comprising such. As evidenced from the specification in Figure 49 several of the 1G8, 3C5, 2H9, 4A10, 3E6 bind the same epitope as 2A2 and 3 G3." (see paragraph 21).

Reiter et al. (WO98/40403) reflects inventors' own work and Drs. Reiter and Witte are listed as co-authors of this reference. Applicants submit a Declaration under 37 C.F.R. §1.132 of Robert Reiter and Owen Witte verifying that the teachings in this reference are their own work (attached herewith as Exhibit 1). All claims were commonly owned by the Assignee, The Regents of the University of California, because these inventors have assigned their rights in the intellectual property to The Regents. This rejection is now moot.

With submission of the Declaration of Drs. Witte and Reiter, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 53, 56-62, 87, 88, 89, 90, 91, 92-94, 95, 96-97, 98 under 35 U.S.C. §102(a).

REJECTION UNDER 35 U.S.C. §102(b)

In paragraph 22, the Patent Office rejects claim 99 under 35 U.S.C. §102(a), as being anticipated by Au-Young (U.S. Patent No. 5,856,136). Specifically, the Examiner stated that "[t]he claim recites a monoclonal antibody that binds amino acid residues 85-123 of SEQ ID NO.:2" and that "Au-Young teach a protein that is identical to SEQ ID NO:2, PSCA except for one amino acid at position 49 . . . it would be inherent that antibodies to the C-terminus would be antibodies that bind to residues 85-123 of SEQ ID NO:2".

Applicants traverse the rejection. A claimed invention is anticipated if each and every element of the claimed invention is disclosed in a single prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the invention in possession of the public. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. Denied* 469 U.S. 851 (1984); In re Donohue, 226 U.S.P.Q. 619 (Fed. Cir. 1985); Scripps Clinic & Research Found. V. Genentech, Inc., 927 F. 2d 1565, 1576-7 (Fed. Cir.), clarified, on recons., 1991 U.S. App. LEXIS 33,486 (Fed. Cir. 1991). The claimed invention must be *identically* disclosed within the four corners of one, and only one, piece of prior art, Scripps Clinic & Research Found. V. Genentech, Inc., 927 F. 2d 1565, 176 (Fed. Cir. 1991).

No where does Au-Young specify any useful fragments of SEQ ID NO: 2, let alone a fragment consisting of amino acid positions 85-123 of SEQ ID NO:2. Nothing in Au-Young suggests the use of the claimed fragments (i.e. any function of the fragments). Furthermore, Au-Young teaches away from the claimed fragment consisting of amino acid

position 85-123 of SEQ ID NO: 2. This is because Au-Young discloses in Figure 5, that the SCAH-2 (e.g. about amino acid 91-123) is hydrophobic.

A skilled artisan would avoid selecting hydrophobic regions for making antibodies because a hydrophobic region is expected to be membrane-bound and thus hidden; and as such therefore not accessible to binding by a cell-surface antibody. Thus, a skilled artisan would use Au-Young's Figure 5 and conclude that the C-terminus (e.g., about amino acids 91-123) is hydrophobic and would not select any fragment within the C-terminus region of SCAH-2 to generate antibodies. The claimed fragment having amino acids 85-123 is included within Au-Young's C-terminal fragment. Therefore, the skilled artisan would not select the claimed fragment to generate an antibody. Without specifically identifying and teaching the claimed fragment, Au-Young cannot be used to demonstrate anticipation under 35 U.S.C. §102.

Accordingly, the rejection is improper and should be withdrawn.

REJECTION UNDER 35 U.S.C. §103

In paragraph 23, the Patent Office rejects claim 53, 56-62, 87-89, 91, 95 and 98 under 35 U.S.C. §103(a) in view of Reiter et al. (WO/40403).

As stated above, in reference to the §102(a) rejection, Reiter et al. (WO98/40403) reflects the inventors' own work and Drs. Reiter and Witte are listed as co-authors of this reference. Applicants submit herewith a Declaration under 37 C.F.R. §1.132 (Exhibit 1) of Robert Reiter and Owen Witte, verifying that the teachings in this reference are their own work. All claims were commonly owned by the Assignee, The Regents of the University of California, because the inventors have all assigned their rights in the intellectual property to The Regents. This rejection is now moot.

With submission of the Declaration of Drs. Witte and Reiter, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 53, 56-62, 87-89, 91, 95, 98 under 35 U.S.C. §103(a).

Further, the Patent Office rejects claim 88 because this claim does not positively recite the kit ingredients/elements that would distinguish claim 88 over the references.

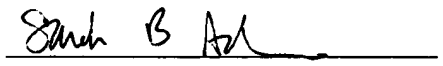
Applicants respectfully disagree. To the extent that the antibody of claim 53 is novel and non-obvious, then a kit comprising such an antibody must also be novel and non-obvious.

CONCLUSION

The arguments set forth above and the attached declaration should remove all prior art rejections as to the pending claims. Claim 99 is additionally rejected under 35 U.S.C §112, first paragraph but the rejection also should be withdrawn in view of the arguments hereinabove. Further, claims 53, 56-62, and 87-99 were rejected under 35 U.S.C. §112, second paragraph but the rejection should be withdrawn in view of the claim changes. Accordingly, Applicants contend that the subject application is in condition for allowance and Applicants request issuance of a notice of allowance.

No fee, other than $205.00 is due in connection with this Amendment. However, if any additional fee is deemed necessary, applicants authorize the Patent Office to charge the fee to the Deposit Account No. 50-0306.

Respectfully submitted,



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